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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 10/650,349 | 08/28/2003 | Steven K. Gelder | 1328-001 | 6672 |
| 4678 | 7590 | 09/20/2005 | EXAMINER | |
| MACCORD MASON PLLC 300 N. GREENE STREET, SUITE 1600 P. O. BOX 2974 GREENSBORO, NC 27402 | | | LYLES IRVING, CARMEN V | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1731 |
| DATE MAILED: 09/20/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/650,349 | GELDER, STEVEN K. |
| | Examiner | Art Unit |
| | Carmen Lyles-Irving | 1731 |

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 August 2003.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) 11-15 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/28/2003.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: ____ .

DETAILED ACTION

Claim Objections

Claims 11-15 are objected to for failing to positively recite any specific method steps. As a result, the examiner has not considered these claims. Appropriate action is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1,3-8

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mascarelli et al (U.S. Patent No. 5,048,544) in view of Beer (U.S. Patent No. 3,208,405) and Holgate (U.S. PG Pub. 2004/0115244). Regarding claims 1 and 3, Mascarelli teaches a device for drug delivery composed of edible matter (the use of a cigarette substitute comprising an edible lollipop containing a smoking substitute composition having nicotine) (claim 1). Mascarelli fails to teach this device with at least two different juxtaposed layers of edible matter. However, Beer teaches it is conventional in the art for lollipops to have two different juxtaposed layers of edible matter (column 2, lines 34-39). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Mascarelli and Beer in order to invent a device for drug delivery comprising two layers of juxtaposed layers of edible matter. Mascarelli and Beer fail to teach a device for drug delivery where each layer of the

device has a dosage level of medication and the layers alternate dosage level. However, Holgate teaches a composition in the form of a lollipop to reduce nicotine cravings as a part of a smoking cessation program (page 1, para. 0010, lines 1-4). Holgate teaches that the concentration of the nicotine in the lollipop can be altered, i.e. multiple layers of nicotine with varying concentrations of nicotine (page 1, para. 0012, lines 10-11; page 2, para. 0022, lines 4-6). It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the teachings of Mascarelli and Beer with the teachings of Holgate to produce a drug delivery device, a lollipop, with multiple layers of edible matter and alternating dosage levels of nicotine. Accordingly, claims 1 and 3 are rejected.

Regarding claims 4, 5 and 6, Mascarelli teaches a support device, that is a lollipop stick, for hand control or manipulation of the device larger than a normal candy support device in order to satisfy a cigarette user's tactile needs (column 3, line 33 – column 4, line 1). Accordingly, claims 4, 5 and 6 are rejected.

Regarding claims 7 and 8, Beer teaches it is conventional in the art for a lollipop to have a chewing gum core (column 2, lines 34-39). Beer fails to teach that the core as one dose level of the drug. However, Holgate teaches that the concentration of the nicotine in the lollipop may be altered and that the concentration of the drug in relation to the candy base may be varied (page 1, para. 0012, lines 10-11; page 2, para. 0022, lines 4-6). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Holgate to produce a drug delivery device with

one dose level in the drug, even in its chewable gum core. Accordingly, claim 7 is rejected.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mascarelli, Beer and Holgate as applied to claim 1 above, and further in view of Jani (U.S. PG Pub. 2002/014059). Mascarelli, Beer and Holgate fail to teach a drug delivery device where there are more than two layers of edible matter and wherein the layers alternate dosage levels. However, Jani teaches a three-layer lollipop (more than two layers of edible matter). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Mascarelli, Beer, and Holgate with the teachings of Jani to achieve a drug delivery device with more than two layers of edible matter where the layers alternate dosage levels. Accordingly, claim 2 is rejected.

9 10
Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mascarelli, Beer and Holgate as applied to claim 1 above, and further in view of Terrero (U.S. Patent No. 6,900,242) and the applicant's admission. Mascarelli, Beer and Holgate fail to teach a device for drug delivery comprising an outer-layer drug that is an anti-side effect drug directed toward alleviating side-effects of an inner-layer, chemotherapeutic drug. However, Terrero teaches the use of lactones to treat cancer (column 8, lines 35-43). Terrero teaches that this lactone may be administered orally through the use of a lollipop (claim 10). The applicant admits that certain chemotherapeutics induce nausea, and therefore an anti-nausea drug is frequently administered prior to administration of the chemotherapeutic to reduce the nausea

(specification, page 9, lines 7-8). As a result, it would have obvious to one of ordinary skill in the art at the time of the invention to have combined the teachings of Mascarelli, Beer and Holgate with the teachings of Terrero and the applicant's admission to create a drug delivery device with an outer layer of anti-nausea drug and an inner-layer of chemotherapeutic drug to reduce the chemotherapy induced nausea in cancer patients in one device. Accordingly, claims 9 and 10 are rejected.

Conclusion

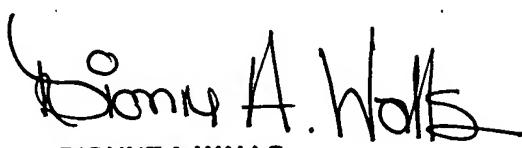
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Byas-Smith (U.S. Patent No. 5,762,963); Sacks et al (U.S. PG Pub. 2004/0265359); Barreca (U.S. PG Pub. 2004/0037788); and Lippens (Des. 390,685).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carmen Lyles-Irving whose telephone number is (571) 272-2945. The examiner can normally be reached Monday through Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steve Griffin can be reached on 571-272-1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLI
09/14/05


DIONNE A. WALLS
PRIMARY EXAMINER